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General Note
Article is recommended to print as digital color version in recycled paper.

COTELLIC (COBIMETINIB)

Company: Genentech; Approved by November 2015

Specific Treatments: BRAF V600E or V600K melanoma

General Information
Cotellic is specifically indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. It is supplied as a tablet for oral administration. The recommended dose is 60 mg (three 20 mg tablets) orally taken once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity. Take Cotellic with or without food. If a dose is missed or if vomiting occurs when the dose is taken, resume dosing with the next scheduled dose.

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Mechanism of Action
Cotellic (cobimetinib) is a reversible inhibitor of mitogen-activated protein kinase (MAPK)/extracellular signal regulated kinase 1 (MEK1) and MEK2. MEK proteins are upstream regulators of the extracellular signal related kinase (ERK) pathway, which promotes cellular proliferation. BRAF V600E and K mutations result in constitutive activation of the BRAF pathway which includes MEK1 and MEK2.

Side Effects
Adverse effects associated with the use of Cotellic may include: diarrhea, sensitivity to ultraviolet light, nausea, pyrexia, vomiting

DARZALEX (DARATUMUMAB)

Company: Janssen Biotech; Approved by November 2015

Specific Treatments: multiple myeloma

General Information
Darzalex is specifically indicated for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. It is supplied as a solution for intravenous infusion. The recommended dose of Darzalex is 16 mg/kg body weight administered as an intravenous infusion

Mechanism of Action
CD38 is a transmembrane glycoprotein (48 kDa) expressed on the surface of hematopoietic cells, including multiple myeloma and other cell types and tissues and has multiple functions, such as receptor mediated adhesion, signaling, and modulation of cyclase and hydrolase activity. Daratumumab is an IgG1κ human monoclonal antibody (mAb) that binds to CD38 and inhibits the growth of CD38 expressing tumor cells by inducing apoptosis directly through Fc mediated cross linking as well as by immune-mediated tumor cell lysis through complement dependent cytotoxicity (CDC), antibody dependent cell mediated cytotoxicity (ADCC) and antibody dependent cellular phagocytosis (ADCP). Myeloid derived suppressor cells (MDSCs) and a subset of regulatory T cells (CD38+Tregs) express CD38 and are susceptible to daratumumab mediated cell lysis.

Side Effects
Adverse effects associated with the use of Darzalex may include: infusion reactions, fatigue, nausea, back pain, pyrexia, cough, upper respiratory tract infection

FLUAD (TRIVALENT INFLUENZA VACCINE)

Company: Seqirus; Approved by November 2015

Specific Treatments: influenza A and B

General Information
Fluad is specifically indicated for the prevention of seasonal influenza in people 65 years of age and older. It is supplied as a solution for intramuscular injection. The recommended dose is a single 0.5 mL dose.

Mechanism of Action
Fluad is a trivalent vaccine produced from three influenza virus strains (two subtype A and one type B). It is manufactured using an egg-based process and is formulated with the adjuvant MF59, an oil-in-water emulsion of squalene oil.

Side Effects
Adverse effects associated with the use of Fluad may include: injection site pain, tenderness

EMPLICITI (ELOTUZUMAB)

Company: Bristol-Myers Squibb; Approved by November 2015

Specific Treatments: multiple myeloma patients who have received prior therapies

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General Information
Empliciti is specifically indicated for use in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies. It is supplied as a solution for intravenous administration. The recommended dose is 10 mg/kg administered intravenously every week for the first two cycles and every 2 weeks thereafter in conjunction with the recommended dosing of lenalidomide and low-dose dexamethasone. Continue treatment until disease progression or unacceptable toxicity.

Mechanism of Action
Empliciti (elotuzumab) is a humanized IgG1 monoclonal antibody that specifically targets the SLAMF7 (Signaling Lymphocytic Activation Molecule Family member 7) protein. SLAMF7 is expressed on myeloma cells independent of cytogenetic abnormalities. SLAMF7 is also expressed on Natural Killer cells, plasma cells, and at lower levels on specific immune cell subsets of differentiated cells within the hematopoietic lineage. Elotuzumab directly activates Natural Killer cells through both the SLAMF7 pathway and Fc receptors. Elotuzumab also targets SLAMF7 on myeloma cells and facilitates the interaction with Natural Killer cells to mediate the killing of myeloma cells through antibody-dependent cellular cytotoxicity (ADCC).

Side Effects
Adverse effects associated with the use of Empliciti may include: fatigue, diarrhea, pyrexia, constipation, cough, peripheral neuropathy, nasopharyngitis, upper respiratory tract infection, decreased appetite, pneumonia

NUCALA (MEPOLIZUMAB)

Company: GlaxoSmithKline; Approved by November 2015

Specific Treatments: severe asthma

General Information
Nucala is specifically indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. It is supplied as an injection for subcutaneous administration. The recommended dose is 100 mg administered once every 4 weeks by subcutaneous injection into the upper arm, thigh, or abdomen.

Mechanism of Action
Nucala (mepolizumab) is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa). IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. Mepolizumab binds to IL-5 with a dissociation constant of 100 pM, inhibiting the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface. Inflammation is an important component in the pathogenesis of asthma. Multiple cell types and mediators are involved in inflammation. Mepolizumab, by inhibiting IL-5 signaling, reduces the production and survival of eosinophils; however, the mechanism of mepolizumab action in asthma has not been definitively established.

Side Effects
Adverse effects associated with the use of Nucala may include: headache, injection site reaction, back pain, fatigue

TAGRISSO (OSIMERTINIB)

Company: AstraZeneca; Approved by November 2015

Specific Treatments: EGFR T790M mutation positive non-small cell lung cancer

General Information
Tagrisso (osimertinib) is an EGFR-TKI, a targeted cancer therapy, designed to inhibit both the activating, sensitizing mutations (EGFRm), and T790M, a genetic mutation responsible to EGFR-TKI treatment resistance. It is specifically indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer, as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. It is supplied as a tablet for oral administration. The recommended dose is 80 mg tablet once a day until disease progression or unacceptable toxicity. It can be taken with or without food. If a dose is missed, do not make up the missed dose and take the next dose as scheduled.

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Mechanism of Action
Tagrisso (osimertinib) is kinase inhibitor of the epidermal growth factor receptor (EGFR), which binds irreversibly to certain mutant forms of EGFR (T790M, L858R, and exon 19 deletion) at approximately 9-fold lower concentrations than wild-type.

Side Effects
Adverse effects associated with the use of Tagrisso may include: diarrhea, rash, dry skin, nail toxicity

PORTRAZZA (NECITUMUMAB)

Company: Eli Lilly; Approved by November 2015

Specific Treatments: metastatic squamous non-small cell lung cancer

General Information
Portrazza (necitumumab) is an epidermal growth factor receptor (EGFR) antagonist. It is specifically indicated for use in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer. It is supplied as a solution for intravenous administration. The recommended dose is 800 mg administered as an intravenous infusion over 60 minutes on Days 1 and 8 of each 3-week cycle prior to gemcitabine and cisplatin infusion. Continue until disease progression or unacceptable toxicity.

Mechanism of Action
Portrazza (necitumumab) is a recombinant human lgG1 monoclonal antibody that binds to the human epidermal growth factor receptor (EGFR) and blocks the binding of EGFR to its ligands. Expression and activation of EGFR has been correlated with malignant progression, induction of angiogenesis, and inhibition of apoptosis. Binding of necitumumab induces EGFR internalization and degradation in vitro. In vitro, binding of necitumumab also led to antibody-dependent cellular cytotoxicity (ADCC) in EGFR-expressing cells.

Side Effects
Adverse effects associated with the use of Portrazza may include: rash, hypomagnesemia

NINLARO (IXAZOMIB)

Company: Millennium Pharmaceuticals; Approved by November 2015

Specific Treatments: Multiple myeloma

General Information
Ninlaro is specifically indicated for use in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. It is supplied as a capsule for oral administration. The recommended starting dose of Ninlaro is 4 mg administered orally once a week on Days 1, 8, and 15 of a 28-day treatment cycle. The recommended starting dose of lenalidomide is 25 mg administered daily on Days 1 through 21 of a 28-day treatment cycle. The recommended starting dose of dexamethasone is 40 mg administered on Days 1, 8, 15, and 22 of a 28-day treatment cycle. It should be taken once a week on the same day and at approximately the same time for the first three weeks of a four week cycle. It should be taken at least one hour before or at least two hours after food. The whole capsule should be swallowed with water. The capsule should not be crushed, chewed or opened. If a dose is delayed or missed, the dose should be taken only if the next scheduled dose is ≥ 72 hours away. A missed dose should not be taken within 72 hours of the next scheduled dose. A double dose should not be taken to make up for the missed dose. If vomiting occurs after taking a dose, the patient should not repeat the dose.

Mechanism of Action
Ninlaro (ixazomib) is a proteasome inhibitor. Ixazomib preferentially binds and inhibits the chymotrypsin-like activity of the beta 5 subunit of the 20S proteasome. Ixazomib induced apoptosis of multiple myeloma cell lines in vitro. Ixazomib demonstrated in vitro cytotoxicity against myeloma cells from patients who had relapsed after multiple prior therapies, including bortezomib, lenalidomide, and dexamethasone. The combination of ixazomib and lenalidomide demonstrated synergistic cytotoxic effects in multiple myeloma cell lines. In vivo, ixazomib demonstrated antitumor activity in a mouse multiple myeloma tumor xenograft model.

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Side Effects

Adverse effects associated with the use of Ninlaro may include: diarrhea, constipation, thrombocytopenia, peripheral neuropathy, nausea, peripheral edema, vomiting, back pain.

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